May 19, 2017

Ms. Ana Corado
Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

ELECTRONIC SUBMISSION VIA REGULATIONS.GOV

Re: Docket ID No. EPA-HQ-OPPT-2016-0231

Dear Sirs:

I strongly support the Agency's approach to restricting some of the applications for which methylene chloride (MeCl$_2$) is needlessly risky to members of the general public and workers. As these comments will demonstrate, EPA has *underestimated* both the levels of exposure and the carcinogenic potency of MeCl$_2$, which in light of the availability of substitute (chemical and physical) methods for paint and coating removal, makes this action even more necessary and wise. As an expert in quantitative risk assessment (QRA) and administrative law, and as one of the very few individuals who has been both the chief regulator and a senior enforcement official at OSHA, I am confident that EPA's proposed rule rests on a very solid scientific, economic, and legal footing, and therefore that any substantial weakening of the rule at this point would be vulnerable to remand as arbitrary and capricious and/or unsupported by the record.

By way of background, I led the development of OSHA's MeCl$_2$ standard, promulgated in final form in 1997. I am also one of three individuals chosen to serve on both of the National Academy of Sciences committees convened in 1994 and 2008 to review EPA's risk assessment methods subsequent to the 1983 publication of the NAS "Red Book," and have served on the EPA Science Advisory Board and the Board of Scientific Counselors, so I have a long-standing interest in how EPA conducts QRA, whether it does so in ways similar to or differently from my former agency. I am also co-editor of a recent book on the impacts of environmental regulations on employment (www.doesregulationkilljobs.org); EPA's conclusion (p. 7473 of the proposed rule) that "the direction of change in employment is uncertain, but EPA expects the short-term and longer-term employment effects to be small" comports with all of the scholarship we included in that volume.

In these comments, I will refer occasionally to a Powerpoint presentation that the Halogenated Solvents Industry Alliance (HSIA) made at a meeting they requested with Office of Information and Regulatory Affairs staff late last year;[1] I am concerned that some of the information in that presentation is incorrect and misleading.

I offer five major points about exposure assessment, dose-response assessment, and risk management issues:

1.   *EPA Underestimates the MeCl$_2$ Exposures Workers and Others are Currently Experiencing.*

EPA bases all of its conclusions about current exposure on a very limited set of monitoring data, while ignoring the largest and most useful dataset in existence: the personal and area air samples OSHA has collected over the past 40+ years. Much of this dataset can be found on the OSHA website, but I obtained a more complete set of measurements and ancillary datafields through a successful FOIA lawsuit in 2007 (Finkel v. U.S. Dep't of Labor, No. 05-5525, 2007 U.S. Dist. LEXIS 47307 (D.N.J. June 29, 2007)).

In a separate (.xlsx) file, I provide information on **12,152** personal air samples OSHA collected on MeCl$_2$ between 1984 and 2016. By contrast, I note that Table G-2 in the EPA risk assessment summarizes fewer than 100 data points found in the published literature. EPA also provides information on about 120 samples (Table G-12) OSHA collected, but this summarizes the *wrong OSHA dataset.* EPA queried the "IMIS" dataset, but that is primarily a compendium of compliance information—analytic results from air sampling are only occasionally and idiosyncratically added to IMIS, which explains why the file I submitted has roughly 100 times the sample size. The correct dataset is the one I received under FOIA—the "SLCTC" (Salt Lake City Technical Center) dataset containing over 2.6 million samples for all substances.

Note that the dataset I've provided *includes* all the non-detects, which EPA reasonably deleted from its analysis. But I believe that most of the establishments where MeCl$_2$ was

---

sampled for probably *did* represent places where it was used, and so including all non-detects biases the results *downwards,* to be conservative in the conclusions I will draw.

HSIA claims (notes to Slide 14) that "there is no basis for EPA to assume that DCM is being used throughout the United States in what would be flagrant violation of the OSHA standard." This is clearly untrue: indeed, *such violations are rampant and happening before OSHA's eyes.* The data I've provided show that the AVERAGE MeCl$_2$ concentration from 1984 to April 1999 (at which point our 1997 standard took full effect) was about 85 ppm, but the average since then has only dropped to 72 ppm! HSIA offers sarcastically (Slide 8) that "it is remarkable EPA would even consider using pre-1997 exposure data," but the full dataset (see the Figure below) shows that while the cumulative distribution of exposures has shifted slightly downward since the standard was promulgated, the pre-1999 and post-1999 distributions are more similar than different. *Even considering only the post-1999 distribution, more than 5% of all samples taken since then exceed 160 ppm, and more than one-third of all samples exceed the 25 ppm PEL.* THIS is the basis for assuming that in fact, there are "flagrant [and, I would add, widespread] violations of the OSHA standard" in the recent past, at this moment, and for the foreseeable future given the number of establishments, the paucity of OSHA inspectors by comparison, and the weakness of the OSHA penalty system.
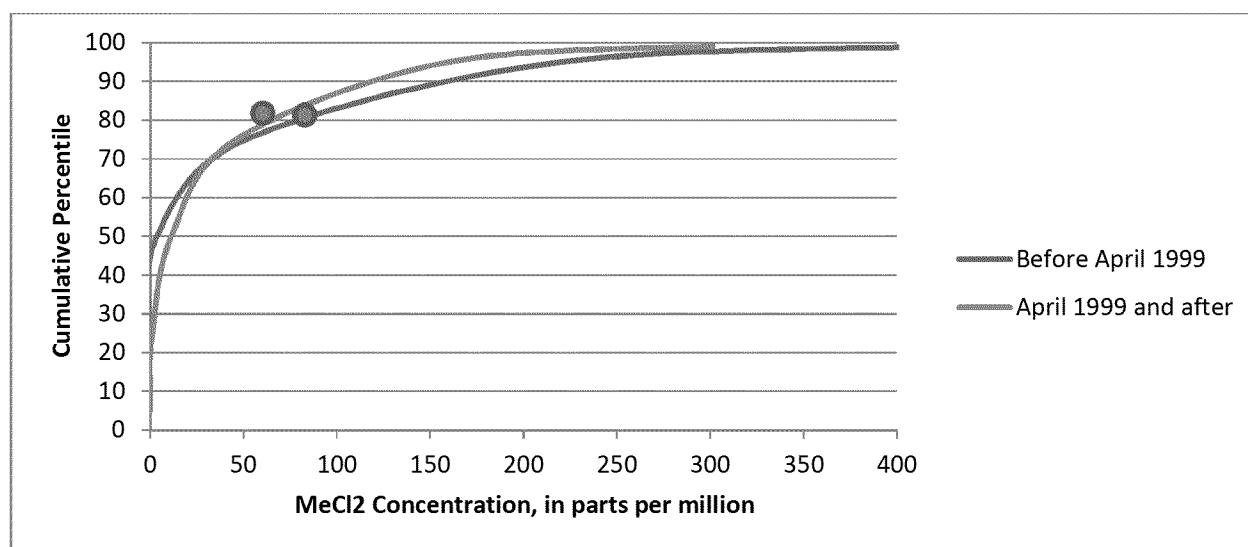
Appendix G of EPA's risk assessment (p. 206) says that it didn't use OSHA "IMIS" data because these data exhibit a "lack of randomness." Presumably, EPA and/or critics would offer the same objection to this much larger SLCTC dataset, but I believe both these bits of

"conventional wisdom" are unwarranted. As an industrial hygienist and former OSHA Regional Administrator, I find the notion that OSHA air sampling data are biased upwards to be facile. OSHA receives very few employee complaints about health issues (as opposed to safety hazards), and inspections within the sectors it targets for inspection are (by law) *random,* not aimed at likely violators. Counteracting the tendency (if it exists) for OSHA to gravitate towards less-compliant facilities is the strong *downward* bias inherent in the fact that OSHA does not tend to inspect very small (10 or fewer employees) establishments in proportion to their abundance in the economy; these facilities tend to have higher chemical exposures, and they are *especially* abundant in the paint/coating SICs.

Since the SLCTC dataset is essentially the only large such compendium in existence, it is impossible to prove or disprove the counterfactual that a truly representative dataset would show systematically lower exposures. But even if the SLCTC data are biased upward, that does not diminish their utility for showing: (1) that the OSHA MeCl$_2$ standard has clearly not caused overall exposures to decline as markedly as HSIA claims it did; and (2) that *substantial* exposures remain. Simply put, so what if the percentiles I've provided in the Figure and in the dataset are biased upward due to nonrepresentativeness, such that fewer than one-third of all current exposures exceed the 25 ppm PEL? Even if the "correct" calculation was that 20%, or even 10%, of all exposures still exceed the PEL (considering the "cleaner" establishments OSHA purportedly did not inspect in their requisite proportions), this still proves that **OSHA has not managed to come close to eliminating unreasonable risk to workers.** EPA has responsibilities to populations that OSHA does not and cannot cover (see below), but clearly even within the subset of OSHA-covered workers there is no "Mission Accomplished" that would allow EPA to regard its proposed restrictions as unnecessary.

2.   *EPA may be Underestimating the Carcinogenic Potency of MeCl$_2$.*

EPA's cancer unit risk estimate for MeCl$_2$ (page 271 of the TSCA risk assessment; EPA 740-R1-4003) is 3.47x10^{-5} per ppm (rounded up to 4E-5). By contrast, OSHA's 1997 risk assessment estimated a working-lifetime excess risk of 3.62x10^{-3} at the 25 ppm PEL, which corresponds to 1.45x10^{-4} per ppm, assuming a linear dose-response between 25 and 1 ppm. The OSHA unit risk value pertains to occupational exposures, and would have to be adjusted to environmental exposures: if one adjusts by (20 m^3/day breathing rate)÷(10 m^3/day)*(70 years of life/45 year working life)*(365 days/year) ÷(250 workdays/year),

the resulting potency estimate becomes 6.6x10^{-4} per ppm. *This is about 15-fold higher than EPA's potency estimate.*

Both agencies computed carcinogenic potency from the same data set (NTP bioassay; female mouse lung tumors), so the large difference must be due to divergent parameter values or science-policy choices. Indeed, one might expect the EPA potency estimate to be *larger* than ours at OSHA, because EPA used the lower bound of the point of departure (BMDL$_{10}$) while OSHA used the maximum likelihood estimate of the multistage dose-response model. But more influential, I believe, is that EPA used a deterministic PBPK model and allometric scaling to estimate human-equivalent doses, and then used a Monte Carlo PBPK model to estimate potency for the mean of the "most sensitive genotype." By contrast, OSHA used a probabilistic PBPK model at both stages, with a set of Bayesian prior distributions for each parameter in mice and humans; we then estimated potency for the upper 95th percentile of the entire working population (rather than stratifying by genotype).

I am not suggesting that EPA redo its calculations—only to acknowledge that its potency factor may be an underestimate, *and that as a consequence the prevailing risks from MeCl$_2$ in paint/coating removal may be even* **more unreasonable** *that the Agency has stated.* I disagree with the HSIA contention (notes to Slide 1) that the EPA risk assessment is "very inadequate"—it is a technically sound assessment, but if it has a bias, it may well be understating risk.

HSIA (Slide 13) implies that EPA's suggestion (that acceptable MeCl$_2$ exposure might be 0.2 ppm) is ambitious or draconian because it is "125 times lower" than the OSHA PEL. But because the two agencies use dramatically different risk targets (OSHA, under the 1980 Supreme Court *Benzene* decision, is allowed to define "insignificant risk" as anywhere between 10^{-9} and 10^{-3}, but has always declined to use anything other than the uppermost end of this range, while EPA tends to shoot for 10^{-4} to 10^{-6}, by custom and by explicit statutory instruction), one would *expect* an EPA "PEL" to be *at least as low as* 1/125 of an OSHA PEL, if not a lower limit than that. Therefore, my concern that EPA is underestimating carcinogenic potency relative to OSHA's assessment makes the 1:125 ratio *even more suspect,* as some of the divergence may be due to different calculations, rather than to the additional protection Congress and the public rightly expects EPA to offer (in other words, the risk is higher than EPA thinks it is at 0.2 ppm).

3.   *Contrary to HSIA's Assertions, EPA has Ample Statutory Authority to Promulgate this Rule.*

HSIA's legal argument (notes to Slide 18) is unfounded. Clearly, the OSHA standard is not sufficiently broad to reduce unreasonable risk under TSCA §9(a): OSHA does not cover public-sector workers in most states, and more importantly, does not cover *independent contractors,* a large and growing segment of the workforce and very relevant to paint/coating removal, especially in construction. Besides, many exposures to MeCl2 from paint/coating removal involve bystanders, do-it-yourselfers, and others in the general public who have no expectation whatsoever of protection under an OSHA rule, and whose exposures can be even higher than those to employees who receive training and follow sensible work practices.

Moreover, the OSHA standard I helped develop, unfortunately, *has failed to eliminate unreasonable risk even for those workers it does cover.* In part, this was due to our failure to set the legally proper PEL in the first place. When we completed our revised risk assessment in 1996, showing that the excess lifetime cancer risk at the 25 ppm PEL was more than three times higher than the uppermost boundary the Supreme Court set for unreasonable risk (1/1000), I was told by our chief economist that it was too late for the economists to analyze the economic feasibility of a lower PEL (10 ppm, by our reckoning, would have been very close to meeting the 1/1000 upper target). Indeed, the final OSHA economic analysis (FEA) admits as much: page VI-35 of the FEA (available at https://www.regulations.gov/document?D=OSHA-H071B-2006-0839-0121) states that "OSHA does not at this time have sufficient evidence in this record to demonstrate feasibility across industry" for 10 ppm. In other words, the 25 ppm PEL is NOT the lowest feasible level that meets the Supreme Court target; OSHA never sought to determine whether 10 ppm (or lower) would ALSO be feasible, and in light of the 3.6x10-3 risk estimate at 25 ppm, that failure made the standard impermissibly weak (although this aspect of the standard was never challenged in court and thus came into force and remains so).

Of course, even if OSHA had set a 10 ppm PEL, this would not mean that OSHA had eliminated unreasonable risk to the extent feasible, according to TSCA: it would merely mean that OSHA had reduced excess lifetime risk to below 1/1000, a level *OSHA* deems appropriate but far higher than EPA's targets under TSCA and other "unreasonable risk" statutes such as the Clean Air Act and Safe Drinking Water Act.

So even assuming HSIA is correct when it says that TSCA §9(a) should not be used when another agency has "sufficient[ly] regulated a particular risk," it is clear that OSHA regulation of MeCl$_2$ has been *insufficient,* in breadth and in stringency.

It is also clear that the new TSCA amendments expect EPA to consider risks to workers, since the Lautenberg Act defines "potentially [highly] exposed or susceptible

subpopulation" to include groups "such as infants, children, pregnant women, *workers,* or the elderly" (emphasis added).

4. *EPA Is Correct to Restrict MeCl₂ Uses: OSHA's Experience Shows that Exposure Limits are Difficult to Implement*

In some places in the proposal, EPA requests further comment about regulatory alternatives, including some that would establish exposure limits and respiratory protection programs in lieu of restricting uses. In light of OSHA's difficulty in enforcing even a 25 ppm PEL, and in light of the variety of other effective chemical and physical methods to remove paint and coatings, EPA should use its TSCA authority to effect use restrictions rather than exposure limits. This recommendation is further supported by the special difficulties MeCl₂ poses for respirator users. EPA is correct to require supplied-air respirators, given the rapid breakthrough times of all available respirator cartridges when challenged with MeCl₂. EPA should also consider that air-purifying respirators are particularly problematic for a solvent like MeCl₂, because even if employees use them for short time periods (before the solvent migrates through the entire cartridge), it can be dangerous to don the respirator again without disposing of the old cartridge, as the solvent can continue to migrate during the period of non-use, potentially exposing the worker to a large initial bolus of MeCl₂ when the respirator is reused.

5. *EPA Should move Expeditiously to Restrict Commercial Furniture Stripping with MeCl₂, and to Consider Other Emissive Uses for Restrictions.*

Although it seems clear on a close reading of the proposal that EPA intends to restrict non-commercial use of MeCl₂ for *all* paint/coating removal, including furniture stripping, in light of the fact that this proposal defers final consideration of commercial furniture stripping, it should be made more clear (throughout the document) that the restrictions on "consumer and most types of commercial paint and coating removal" more precisely means "*all consumer uses, including furniture stripping*, and all commercial uses *except* furniture stripping."

I urge the Agency to move expeditiously to restrict use of MeCl₂ for commercial furniture stripping as well; this use exposes workers and others to high concentrations and unreasonable risks. There may, of course, be other uses for MeCl₂ that are better addressed via a use restriction than via a NESHAP, and I urge EPA to continue to explore those uses, especially ones where safer substitutes are readily available.

In conclusion, by EPA's reckoning the risks to workers and the general public amply justify a sensible TSCA rule such as this one, but EPA understates the magnitude of the harm that will continue to accrue if it does not act. On p. 7471, the proposal states that "workers and occupational bystanders exposed to methylene chloride in paint and coating removal have an increase in cancer risk that ranged from 10 times to almost 1,000 times greater than a cancer benchmark of 1 in 1,000,000." This is incorrect: the upper end of the excess risk range is *clearly* above 1/1000. By either EPA or OSHA's unit risk estimate, applied to the current documented distribution of exposures provided above, workers currently face excess cancer risks from $MeCl_2$ approaching 1 chance per 100, or almost **10,000** times the cancer benchmark of 1/1,000,000.

TSCA exists to eliminate unreasonable risk at least insofar as this is easily achieved; 20 years after the OSHA standard, risks to workers covered by the standard are still unreasonable, and risks to all others NOT covered by the standard REMAIN unreasonable.

Thank you for the opportunity to comment on this important issue; I would be happy to provide any further information by request.

Sincerely,

Adam M. Finkel

Adam M. Finkel, Sc.D., CIH
Senior Fellow and Executive Director, Penn Program on Regulation, University of Pennsylvania Law School
and
Clinical Professor of Environmental Health Sciences, Univ. of Michigan School of Public Health

(affiliations listed for purposes of identification only)